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10/588,406	06/11/2007	Jing X. Kang	64624(51588)	8352

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	PAPER NUMBER
1632	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,406	KANG, JING X.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 22-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8-3-06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8-3-06 & 1-5-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group III, claims 20 and 21, in the reply filed on 3-17-09 is acknowledged. The traversal is on the ground(s) that there is no serious burden to search both groups II and III because a search for food product of group III would require a search for the non-human transgenic animal of group II. Upon further consideration of the subject matter of groups II and III, groups II and III will be examined together.

The requirement for the remaining groups is still deemed proper and is therefore made FINAL.

2. Claims 1-16 and 22-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3-17-09.

Applicant's amendment filed 3-17-09 has been entered. Claim 20 has been amended. Claims 1-45 are pending. Claims 17-21 and a non-human transgenic mammal are under consideration.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,238,851 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because although drawn to different scope, they are the same inventions or the variants thereof.

Claims 17-19 of the instant invention are directed to a non-human transgenic mammal comprising the nucleic acid molecule encoding an enzyme that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid, wherein the non-human transgenic mammal is a cow, a pig or a sheep.

Claims 1-16 of US Patent No. 7,238,851 B2 are directed to a nonhuman transgenic mammal whose genome comprises a nucleic acid molecule operably linked to a promoter, wherein the nucleic acid molecule comprises the sequence of SEQ ID No. 3 or encodes the amino acid sequence that is at least 90% identical to SEQ ID No. 4 and the cells of the transgenic mammal exhibits elevated n-3 polyunsaturated fatty acid content as compared to wild-type mammals, and wherein the transgenic mammal is a cow, a pig, a sheep or a mouse. Nucleic acid sequence of SEQ ID No. 3 is C. elegans fat-1 cDNA and encodes the Fat-1 polypeptide.

The C. elegans Fat-1 polypeptide is a desaturase that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid, therefore, claims 17-19 of the instant invention would be prima faci

obvious to one of ordinary skill in the art in view of the disclosure of claims 1-16 of US Patent No. 7,238,851 B2.

Claim Objections

5. Claim 17 is objected to because of the following informalities: Claim 17 depends from nonelected claim 1. It would be remedial to recite the limitations of claim 1 in claim 17. Appropriate correction is required.

Specification

This application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because a copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). There is no sequence listing for the nucleotide sequence and amino acid sequence in Figure 17A-B and Figure 18. Applicant must provide (1) an initial or substitute computer readable form (CRF) copy of the "sequence Listing", (2) an initial or substitute paper copy of the "Sequence Listing"" as well as an amendment directing its entry into the specification, and (3) a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d). Further, there is no sequence identifier for the nucleotide sequence in Figure 17A-B and Figure 18 or in the "BRIEF DESCRIPTION OF THE

DRAWINGS". Each nucleotide sequence is required to have a sequence identifier. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on the use of nucleic acid sequence encoding an enzyme that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid in making non-human transgenic animals. The specification only discloses the nucleotide sequence of C. elegans fat-1 cDNA and the deduced amino acid sequence of the Fat-1 polypeptide. The claims encompass various nucleic acid sequences encoding numerous different Fat-1 polypeptides derived from various mammals, such as humans, mice, rats, chimpanzees, monkeys, horses, sheep, rabbits, pigs, cats, dogs, cows, and whales etc.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 111 1, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1 117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

The specification only discloses the nucleotide sequence of C. elegans fat-1 cDNA and the deduced amino acid sequence of the Fat-1 polypeptide. In the instant case the genus of fat-1 genes encompassed by the claims lack a written description. The specification fails to describe what DNA molecules other than the nucleotide sequence encoding C. elegans Fat-1 polypeptide fall into this genus and it was unknown as of Applicants' effective filing date that any of these DNA molecules would have the property of encoding a Fat-1 polypeptide having the same structural and functional properties as that encoded by the C. elegans fat-1 gene. There is no evidence on the record of a relationship between the structures of the nucleotide sequences coding for any fat-1 gene product and the nucleotide sequence coding for C. elegans Fat-1 polypeptide that would provide any reliable information about the structure of DNA molecules within the genus. The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor has possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646
(1998).

With the exception of the sequence referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid sequences, and therefore conception is not achieved until reduction to practice has occurred regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by any member of the genus of genes encoding a fat-1 gene product other than the described nucleotide sequence encoding C. elegans Fat-1 polypeptide. Therefore, only the nucleotide sequence encoding the C. elegans Fat-1 polypeptide, but not the full breadth of the claims meet the written description provision of 35 U.S.C. 112 first paragraph. Applicants were not in possession, at the time of the invention, of the nucleic acid sequences encoding various Fat-1 polypeptides other than the described sequence encoding the C. elegans Fat-1 polypeptide. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that "to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention".

Applicant is reminded that Vas-Cath makes clear that the written description provision of

35 U.S.C. 112 is severable from its enablement provision (see page 1115).

8. Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic mouse expressing C. elegans Fat-1 polypeptide under the control of chicken beta-actin promoter and cytomegalovirus enhancer, wherein the transgenic mouse exhibits significantly higher level of n-3 fatty acid in tissues disclosed in Table 1 as compared to wild-type mouse, and transgenic zebrafish expressing C. elegans Fat-1 polypeptide under the control of chicken beta-actin promoter and cytomegalovirus enhancer, wherein the transgenic zebrafish exhibits significantly higher level of n-3 fatty acid in muscle tissues as compared to wild-type zebrafish, does not reasonably provide enablement for the generation of numerous different non-human transgenic mammals expressing various Fat-1 polypeptides under the control of various promoters, the use of said non-human transgenic mammals for a food product or dietary supplement, and a method of improving the content of n-3 fatty acids in a subject by using said food product or dietary supplement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considered whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirement, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of

ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d at 737, 8 USPQ2d 1400, 1404 (Fed. Cir.1988)).

Furthermore, the USPTO does not have laboratory facilities to test if an invention with function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raises and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The claims are directed to a non-human mammal comprising a nucleic acid molecule encoding an enzyme that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid and the sequence includes at least an optimized codon, a food product or dietary supplement comprising a tissue or processed part thereof obtained from said non-human transgenic mammal, and a method of improving the content of n-3 fatty acids in a subject's diet by administering to the subject the food product or dietary supplement. Claim 19 recites various transgenic mammals.

The claims encompass tens of thousands of numerous different transgenic non-human mammals, such as mice, rats, rabbits, cows, goats, sheep, horse, pigs, monkeys, whales, and other mammals, having various unknown and unidentified phenotypes. The specification discloses a transgenic mouse expressing C. elegans Fat-1 polypeptide under the control of chicken beta-actin promoter and cytomegalovirus enhancer, wherein the transgenic mouse exhibits significantly higher level of n-3 fatty acid in tissues disclosed in Table 1 as compared to wild-type mouse, and transgenic zebrafish expressing C. elegans Fat-1 polypeptide under the

control of chicken beta-actin promoter and cytomegalovirus enhancer, wherein the transgenic zebrafish exhibits significantly higher level of n-3 fatty acid in muscle tissues as compared to wild-type zebrafish (e.g. Examples 8 and 14). The specification fails to disclose any transgenic non-human mammal, other than the disclosed transgenic mouse and zebrafish, comprising the claimed nucleic acid sequence under the control of different promoters and enhancers, wherein the transgenic non-human mammals exhibit significantly higher levels of n-3 fatty acid as compared to corresponding wild-type mammals.

The state of the art in the fields of transgenic animal at the time of the invention was unpredictable, the transgene expression and resulting phenotype of such expression is not always accurately predictable. Kappel et al., 1992 (Current Opinion in Biotechnology, Vol. 3, p. 548-553) reports that the individual gene of interest, promoter, enhancer, coding or non-coding sequences present in the transgene construct, the site of integration, etc., are the important factors that governs the expression of a transgene (e.g. p. 549)). Wall, R. J., 1996 (Theriogenology, Vol. 45, p. 45-68) states that "[o]ur lack of understanding of essential genetic control elements makes it difficult to design transgenes with predictable behavior" (e.g. p. 61, last paragraph), and "transgene expression and the physiological consequences of transgene products in livestock are not always accurately predicted in transgenic mouse studies" (e.g. p. 62, first paragraph). Promoter and enhancer in a transgene construct play an important role in the expression of said transgene in transgenic animal and expression of same transgene construct could vary in different species.

Sigmund, June 2000 (Arterioscler. Thromb. Vasc. Biol., p. 1425-1429), reports that variation in the genetic background contributes to unpredictable resulting phenotypes of

transgenic or gene-targeted animals. "Animals containing the same exact genetic manipulation exhibit profoundly different phenotypes when present on diverse genetic backgrounds, demonstrating that genes unrelated, per se, to the ones being targeted can play a significant role in the observed phenotype" (e.g. abstract). Sigmund further states that "many of the phenotypes examined in transgenic and knockout models are influenced by the genetic background in which they are studies...Although all mouse strains contain the same collection of genes, it is allelic variation...and the interaction between allelic variants that influence a particular phenotype. These "epigenetic" effects can dramatically alter the observed phenotype and therefore can influence or alter the conclusions drawn from experiments" (e.g. introduction).

In addition, Mercier et al., 1997 ("The modification of milk protein composition through transgenesis: progress and problems," In: Transgenic Animals: Generation and use, Ed. Houdebine LM, Harwood Academic Publishers, The Netherlands pp: 473-482) teach that "much progress remains to be done before routinely using transgenesis for generating farm animals producing milk for non-therapeutic use. In the present state of the art, it is difficult to predict that a construct will be functional because of insufficient knowledge on gene transcript, Pre-mRNA processing, RNA and protein stability. Integration of the microinjected transgene is aleatory resulting in highly variable levels of expression, and possible detrimental effects." (e.g. p. 479, right column).

Goldman et al., 2004 (Med Sci Monit, Vol. 10, No. 11, RA274-285) points out the integration frequency of the transgene in making transgenic animal depends substantially on several parameters such as the form (linear or circular) of the DNA molecule, the DNA concentration, the DNA copy number, and the injection site (male or female pronucleus) (e.g. p.

RA275, right column). Goldman also states that "[a]n important problem in the construction of transgenic animal is that transgene expression achieved with one construct greatly varies among primary transgenic animals or is even absent from some of these". Goldman suggests that the inactive domain of the eukaryotic genome can play a role in the suppression of the transgene expression. When the transgene is integrated into an inactive domain in a chromosome or located in its immediate vicinity said transgene can be inactivated (e.g. RA281, left column). Therefore, the individual gene of interest, promoter, enhancer, coding or non-coding sequences present in the transgene construct, the genetic background of the transgenic mammal, the form (linear or circular) of the DNA molecule, the DNA concentration, the DNA copy number, the injection site, and the integration site of the transgene could determine the transgene expression and resulting phenotype of the transgenic mammal. Generation of transgenic animal with desired phenotype is far from routine experimentation in view of the state of the art of transgenics. It was unpredictable at the time of the invention whether the polypeptide would be expressed or not, where the polypeptide is expressed in the transgenic mammal, if any, to what level it is expressed, whether the expression of said polypeptide is different from that of wild type non-human mammal, and whether the expression of said polypeptide in the biological tissue or transgenic cell would alter or influence the phenotype of the wild type non-human mammal. The claims encompass a vast number of different non-human mammals having dramatically different genetic background. The resulting phenotype of the claimed non-human mammals would be unpredictable at the time of the invention because of the dramatically different genetic backgrounds of the mammals and the factors discussed set forth above.

The claims also encompass using various polynucleotides encoding numerous different polypeptides having activity to desaturate an n-6 fatty acid to n-3 fatty acid. It was well known in the art that different polypeptides would have different biological functions and said different biological functions would contribute to different phenotypes of the claimed non-human mammals. Thus, the resulting phenotype of the vast scope of the claimed non-human mammals expressing numerous different polypeptides was unpredictable at the time of the invention and one skilled in the art at the time of the invention would not know how to use the claimed non-human mammals, for example for food product or dietary supplement to improve the content of n-3 fatty acids in a subject's diet.

The claims also encompass chimeric non-human mammals wherein only a portion of the cells of the mammals comprises the claimed polynucleotide sequence. The specification fails to enable making chimeric non-human mammals such that they exhibit any phenotype, including a wild-type phenotype. The specification fails to disclose any phenotype for the claimed chimeric non-human mammals. The method of making genetic mosaic animal is such that each resulting chimera is comprised of a different, unpredictable ratio of cells of various genotypes. This ratio cannot be predetermined. Furthermore, the spatial distribution of cells of each genotype cannot be predetermined. Therefore, the phenotype of chimeric animals is not only dependent upon the genotype of the cells (which is unpredictable as set forth by the state of the art outlined above, for example, see Goldman; Sigmund; Mercier) but is also dependent upon the spatial distribution of the cells and their relative population size. Thus, the phenotype of the chimeric mammals encompassed by the claims is highly unpredictable. The specification fails to provide the guidance necessary to overcome this high level of unpredictability to generate a chimeric

mammal exhibiting any specific phenotype or any phenotype other than wild type. As set forth above, without a predictable phenotype, it would require additional and undue experimentation for one of skill in the art to determine a useful phenotype for the claimed chimeric non-human mammals. Therefore, without undue experimentation, the skilled artisan would not know how to use the chimeric non-human mammals encompassed by the claims.

Claim 21 reads on improving the content of n-3 fatty acids in a subject's diet by administering to the subject the food product or dietary supplement. The specification fails to provide adequate guidance and evidence for how to "improve" the content of n-3 fatty acids in a subject's "diet" by administering to the subject the "food product" or dietary supplement" via various administration routes, such as intravenous administration, intramuscular injection, intraperitoneal administration, topical administration, and subcutaneous administration etc. It is unclear how to administer a "food product" via intravenous administration, intramuscular injection, intraperitoneal administration, topical administration, and subcutaneous administration etc., to a subject so as to "improve" the content of n-3 fatty acids in said subject's "diet". Absent specific guidance, one skilled in the art at the time of the invention would not know how to practice the claimed invention.

In view of the inherent unpredictability of transgene expression in the transgenic non-human mammals and the unpredictability of the resulting phenotype of the transgenic and chimeric non-human mammals, and the lack of guidance for how to administer a food product to a subject via various administration routes so as to "improve" the content of n-3 fatty acids in said subject's "diet", one skilled in the art at the time of the invention would not know how to

use the claimed non-human mammals, such as to use the transgenic mammal as food product or dietary supplement to improve a subject's diet.

The quantity of experimentation required to practice the instant invention includes identification and isolation of numerous polynucleotide encoding an enzyme that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid, characterization of said enzyme, introduction of said polynucleotide into numerous different non-human mammals including germ cells and somatic cells, generation of various transgenic and chimeric non-human mammals, trial and error experimentation to determine the expression pattern and expression level of the polypeptides in said non-human mammals, and trial and error experimentation to determine the resulting phenotype of said non-human mammals and how to use said non-human mammals as a food product or dietary supplement to improve the content of n-3 fatty acids in a subject's diet.

For the reasons discussed above, it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed. This is particularly true given the nature of the invention, the state of the prior art, the breadth of the claims, the amount of experimentation necessary, the working examples provided and scarcity of guidance in the specification, the level of skilled artisan which is high, and the unpredictable nature of the art.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Mukerji et al., 2007 (US Patent No. 7,211,656 B2).

Claims 17-19 are directed to a non-human mammal comprising a nucleic acid molecule encoding an enzyme that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid and the sequence includes at least an optimized codon. Claim 19 recites various transgenic mammals.

Mukerji teaches isolated polynucleotides encoding an omega-3 desaturase and a delta-12 desaturase, vectors containing said isolated polynucoleotides and transgenic host that contain the isolated polynucleotides that express the enzyme (e.g. abstract). Transgenic mammals, such as mice, rats, rabbits, swine, goats and sheep, may be used to express the enzymes to produce the PUFAs of interest. Milk, tissue, or other fluid samples from the transgenic mammals could contain altered levels of PUFAs as compared to the levels normally found in the non-transgenic animal (e.g. column 15, lines 12-32). Omega-3 desaturase can desaturate an n-6 fatty acid to n-3 fatty acid. Thus, the claims are anticipated by Mukerji.

11. Claims 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang, J. X., 2002 (WO 02/072028 A2, IDS BB).

Claims 17-21 are directed to a non-human mammal comprising a nucleic acid molecule encoding an enzyme that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid and the

sequence includes at least an optimized codon, a food product or dietary supplement comprising a tissue or processed part thereof obtained from said non-human transgenic mammal, and a method of improving the content of n-3 fatty acids in a subject's diet by administering to the subject the food product or dietary supplement. Claim 19 recites various transgenic mammals.

Kang teaches nucleic acids encoding fat-1 operably linked to a constitutively active or tissue-specific promoter and a method to effectively modify the content of PUFAs in animal cells of transgenic animal containing said cells, and food products obtained from those transgenic animals (e.g. meat or other edible parts of the animals such as liver or kidney) (e.g. abstract). Kang teaches an isolated nucleic acid molecule encoding an enzyme that desaturates an omega-6 fatty acid to a corresponding omega-3 fatty acid, and expression vector comprising said nucleic acid, a transgenic mammal comprising said nucleic acid molecule, and a method of improving the content of omega-3 fatty acids in a patient's diet by providing to the patient a food product obtained from a transgenic mammal that express a fat-1 gene or a biologically active fragment or variant thereof (e.g. p. 40, claims 1-7). Thus, the claims are anticipated by Kang.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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